



# Facts & News

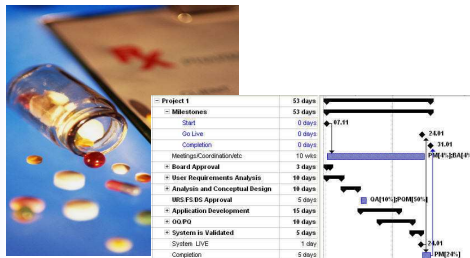
Our last issue of 'Facts & News' was focused on our activities in the Pharmaceutical Industry. This time we would like to present our engagement in the R&D area and how IT can help to make R&D more successful.

**wega** consultants have supported Research & Development Departments in the pharmaceutical and chemical industry for more than 10 years. Here are some recent examples of how our customers can benefit from our experience and know-how.

For more information about wega please refer to [www.wega-informatik.ch](http://www.wega-informatik.ch).

**wega** Management  
**A. Matthijssen, U. Mohaupt, S. Waltenspiel**

## Clinical Development business process improvement



### Continuous process improvement using LEAN SixSigma

**wega** consultants support organizations in the pharmaceutical industry in business process definition and improvement.

One of the **wega** business analysts, a SixSigma Champion, is currently involved in:

- The improvement of Clinical Drug Supply Packaging / Labelling und Distribution using the LEAN SixSigma methodology to ensure the clear definition of objectives and requirements as well as traceability and measurable results.
- In the re-design of R&D data management processes the quality and improvement focused approach of LEAN SixSigma helps to understand the processes and the improvement opportunities to align business processes with strategy.

### eCRF Process Improvement

Elapsed time from final protocol release to first visit is crucial to clinical studies.

**wega** consultants supported a project to dramatically improve the performance of the eCRF development process.

Responsibilities of the **wega**-team included:

- Re-design of the process to allow more flexibility and accuracy.
- Design of a common tool and repository for all data from protocol to submission based on CDISC and HL7 standards.
- Development of an intuitive, easy to use application that supports timely, flexible, and reliable development of eCRF documents in a validated framework.

The use of UML techniques to describe the processes allowed a standard way of representation in an international und multicultural environment.

### Safety Data Sharing Application supports Clinical Studies

Pharmacokinetics (PK) is one of the Areas where the amount of data is a challenge.

To support consistency and reliability and to present a user friendly interface, **wega** consultants developed a web based application to capture and present safety data.

Using standard XML-technology such as XSD (schema), XSLT (Transformation), MS Inference Tool (basis for XSL Stylesheet) as well as J2EE a special report was developed that allows addition of user defined comments and annotations to the presented safety data without losing data integrity.

The system was implemented to customer satisfaction and is now in use.

### New wega Director Life Sciences

Especially when it comes to the interfaces between research and pre-clinical, non validated to validated environment it's important to know the challenges of research as well as clinical development.

Joining **wega** from a global pharmaceutical company **Andreas Dominik** brings more than 10 years of know how and experience in the area of research and pre-clinical processes, supporting IT solutions and validated interfaces in an international environment.

Andreas Dominik will lead the **wega** service line Life Science as Director and provide Pharma R&D consultancy.

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